Health Services
LOS ANGELES COUNTY

October 21, 2008

313 N. Figueroa Street, Suite 912
Los Angeles, CA 90012

Tel: 213-240-8101
Fax:213-481-0503

www.dhs.lacounty.gov

To improve health through leadership, service and education

The Honorable Board of Supervisors
County of Los Angeles
383 Kenneth Hahn Hall of Administration
500 West Temple Street
Los Angeles, California 90012

Dear Supervisors:

PROVISION OF LEGAL REPRESENTATION FOR PHARMACISTS INVOLVED IN A CALIFORNIA STATE BOARD OF PHARMACY CITATION AT LAC+USC MEDICAL CENTER WOMEN AND CHILDREN'S HOSPITAL (SUPERVISORIAL DISTRICT 1) (3 VOTES)

SUBJECT

Request approval to provide legal representation for two Department of Health Services employees related to a California State Board of Pharmacy citation.

IT IS RECOMMENDED THAT YOUR BOARD:

1. Find that LAC+USC Medical Center pharmacist employees, as described below, acted in good faith and without malice in the apparent interests of the County.

2. Delegate authority to the Los Angeles County Counsel to provide legal representation for two pharmacists at LAC+USC Medical Center related to the contest of a citation and fine by the State Board of Pharmacy.

PURPOSE/JUSTIFICATION OF RECOMMENDED ACTION

The Department of Health Services (DHS) is requesting approval, as required by state law, to provide legal representation to two members of the pharmacy department at LAC+USC Medical Center who have each received a citation and fine from the State Board of Pharmacy in relation to a May 8, 2008 Board of Pharmacy inspection.

The May 8 State Board of Pharmacy inspection discovered recalled heparin flush syringes within the LAC+USC Medical Center's Women and Children's

Hospital, leading to a citation and fine for the LAC+USC Medical Center, as well as two involved pharmacists. The inspection results and subsequent citations raise direct questions about actions taken by the LAC+USC Medical Center and these individual pharmacists pursuant to a March 28, 2008 manufacturer recall of heparin flush syringes. Given that the citations involved actions taken in regards to established LAC+USC Medical Center patient care policies, the provision of legal representation to contest these citations is appropriate given that the pharmacists were performing these duties in their scope of employment with the County. In addition, in our preliminary investigation, specific allegations referenced in the inspection results may not be factual in content.

FISCAL IMPACT/FINANCING

Costs will be covered with funds already included in the DHS Fiscal Year 2008-09 Adopted Budget.

FACT AND PROVISIONS/LEGAL REQUIREMENTS

On March 28, 2008, Covidien Pharmaceuticals, a medical device manufacturer, as a result of US Food and Drug Administration (FDA) consultation, issued a press release informing the public that specific lot numbers of their heparin flush syringes were voluntary recalled, "as a precautionary measure", following the FDA's direction. The FDA direction impacted multiple heparin injectable products, and was a result of the possibility of a heparin-like contaminant that might lead to allergic reactions when administered to patients. Although Covidien cited that they had not received any reports of adverse reactions associated with their heparin flush syringes, the FDA had received reports of adverse events associated with other manufacturer's products. As heparin is a generically available product, there are multiple manufacturers that provide this agent in the US commercial market.

Heparin is an anticoagulant, and in therapeutic doses, is utilized to reduce the incidence of clot formulation in the blood. The heparin flush syringes discovered in this recall were not utilized as a therapeutic anticoagulant, but rather to flush the intravenous lines of patients receiving continuous infusion therapy. The heparin flush syringe prevents clot formation in the intravenous line, ensuring that the intravenous line remains patent for future medication administration of other agents. The total heparin dose in each flush syringe is 30 units, significantly far below the therapeutic dose of 200-500 units per hour for a small child.

Due to the fact that there are multiple generic manufacturers for heparin products, most pharmacies rely on purchase history when reviewing drug recall alerts. LAC+USC Medical Center did not receive a recall notification from Covidien, as is required per FDA policy. However, LAC+USC Medical Center did receive a copy of the FDA press release, and subsequently reviewed purchase history. As "Covidien" was not listed as a manufacturer of the multiple heparin products purchased by this pharmacy, the

pharmacist came to the conclusion that this agent was not present within the Medical Center. What was discovered, after the May 8 State Board of Pharmacy inspection, was that Covidien Pharmaceuticals had, in 2007, purchased Kendall Tyco (another medical device manufacturer) and that the "Covidien" recalled syringes were actually labeled with the "Kendall Tyco" manufacturer name.

On May 3, the California Department of Public Health forwarded, via facsimile, a letter to all California hospitals regarding the need to remove recalled heparin from patient care areas. The letter was received by LAC+USC Medical Center leadership, and referenced the following heparin drug manufacturers: "Baxter International, B. Braun, American Health Packaging (AHP) and Covidien." There was no mention of "Kendall Tyco" which was the manufacturer identified on the heparin flush syringes discovered by the Board of Pharmacy during an inspection later that week.

During the month of May 2008, the State Board of Pharmacy inspected 533 licensed hospital pharmacies throughout California. At least one form of recalled heparin was discovered in 94 of these hospitals, within the hospital's medication stock.

On May 8, the State Board of Pharmacy performed an unannounced inspection at the LAC+USC Medical Center. During this inspection, the State Board discovered 21 Kendall-Tyco syringes in the Women and Children's Hospital Pharmacy, and another 108 syringes in a patient care area. At the conclusion of this inspection, the State Board provided multiple actions that were to be taken by the pharmacy in reaction to this finding. The pharmacist in charge complied with all of the actions stated, and provided documentation of such to the State Board of Pharmacy. Notification of this inspection was forwarded to the Health Deputies on May 19, 2008. The LAC+USC Medical Center has indicated that there has been no identified patient impact related to the use of recalled heparin syringes.

On August 20, the State Board of Pharmacy announced that "the California State Board took steps towards citing and fining 94 hospitals and the head pharmacist at each facility for not complying with a recall of the blood thinner heparin and removing the medications from hospital pharmacies."

On September 15, LAC+USC Medical Center Women's and Children's Hospital received notice from the State Board of Pharmacy of the issuance of a citation and $5,000 fine, resulting from the hospital's alleged violation of California Business and Professions Code 4301 and 4169 (a) (2). This citation was issued pursuant to the May 8, 2008 State Board of Pharmacy inspection, where heparin syringes, previously recalled by the drug manufacturer, were discovered in the Women and Children's Hospital pharmacy and pediatric intensive care unit stock.

In addition to receiving a hospital citation and fine, two licensed pharmacists employed by LAC+USC Medical Center were also issued a citation and $5,000 fine each for the same

violations (Business and Professions Code 4301 and 4189 (a)(2)). One of these pharmacists was assigned as the State Board pharmacist-in-charge of this LAC+USC inpatient pharmacy, and the other was assigned as the "audit pharmacist", with a responsibility to oversee LAC+USC Medical Center drug recall efforts.

Our preliminary investigation discovered that our pharmaceutical wholesaler, Cardinal Healthcare, had listed "Kendall Healthcare" rather than "Covidien" as the manufacturer of the identified recalled syringes. As pharmacies receive multiple recalls each week, reliance is placed on review of purchase history to identify impact. Frequently, a specific pharmacy may not be impacted with a drug recall, as the medication was not previously purchased within the recalled time frame. In a Cardinal purchase report issued in March 2008, purchases for "Kendall Healthcare" were listed, but no purchase history was identified for "Covidien Healthcare". It was later discovered that Tyco Healthcare had previously changed its name to Covidien Healthcare, yet the manufactured syringes bore the previous manufacturer name, "Kendall Tyco." In addition, at no time did LAC+USC Medical Center receive official notification from Cardinal Healthcare, Covidien Healthcare, or Kendall-Tyco of this voluntary recall, as required by FDA policy.

The State Board of Pharmacy citations received reference "unprofessional conduct" for both the hospital pharmacy (which includes the hospital administrator on the license) as well as the pharmacist-in-charge on the hospital pharmacy license. This is a serious charge. The citation against each pharmacist is in relation to their individual pharmacist license, and alleges a violation of Business and Professions code that may ultimately impact their ability to renew their license. Given the fact that in order to license a pharmacy within California, a pharmacist must be assigned to place their name on the pharmacy license as "pharmacist-in-charge", the level of responsibility is high. DHS is concerned, given the current pharmacist statewide shortage, that not providing support for pharmacists who act within the scope of their duties will impact recruitment and future ability to ensure that pharmacists accept this responsibility.

State law permits legal representation for an administrative proceeding against a County employee for actions undertaken within the scope of his or her County employment, if it is determined that the employee acted in good faith and without malice in the apparent interests of the County. In addition, such representation must be determined to be in the best interest of the County. The Department has reviewed this matter and believes that given the facts reviewed thus far and the underlying circumstances and roles and responsibilities of the involved pharmacist staff, legal representation is appropriate for the personnel involved, as set forth above.

The Department has previously requested and obtained Board approval on several occasions to provide legal representation of other professional staff (e.g. physicians). Outside counsel, with specific pharmacy law expertise will be engaged by County Counsel through its regular processes.

CONTRACTING PROCESS:

Not applicable.

IMPACT ON CURRENT SERVICES (OR PROJECTS):

The Department believes that it is in the best interests of the County to provide legal representation to the impacted LAC+USC Medical Center pharmacists that have, or may be, cited by this specific State Board of Pharmacy issue in order to ensure that they continue to oversee our licensed pharmacies. In addition, it will demonstrate that the County intends on supporting pharmacists that volunteer to place their personal pharmacist licenses on the County pharmacy license, act within the scope of their duties, thus allowing the Department to continue pharmacy operations for patient care.

When approved, DHS requires three signed copies of the Board's action

Respectfully submitted,

John F. Schunhoff, Ph.D.
Interim Director

JFS:ag

c: Chief Executive Officer
County Counsel
Executive Officer, Board of Supervisors